II. REMARKS

A. Introduction

Applicant submits this Response in a bona fide attempt to (i) advance the prosecution of this case, (ii) answer each and every ground of objection and rejection as set forth by the Examiner, (iii) place the claims in a condition for allowance, and (iv) place the case in better condition for consideration on appeal. Applicant respectfully requests reexamination and reconsideration of the above referenced patent application in view of this Response.

B. Priority Claim

As indicated above, the instant application is a continuation-in-part of U.S. Application No. 09/684,104, now U.S. Pat. No. 6,537,225. Applicant is accordingly requesting that the application be amended to reflect the noted reference to the prior filed, related application.

On May 15, 2003, Applicant also submitted a Petition to the PTO Office of Petitions to accept the unintentionally delayed priority claim to U.S. Application No. 09/684,104. A copy of the Petition and a duly executed Substitute Declaration, claiming priority to the noted application, are enclosed herewith.

C. Response to Restriction Requirement

In response to the Restriction Requirement, Applicant hereby elects Specie I, with traverse. Specie I is directed to a method for determining the concentration of a blood constituent while varying the volume of blood.

Applicant respectfully submits that pending Claims 1-6, 53 and 55, and new Claims 56 - 61 read on the noted Specie.

D. Response to Rejections

The Examiner has rejected Claims 1-6, 53 and 55 "under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent 5,638,816 to Kiani-Azarbayjany et al." The Examiner contends:

> Kiani-Azarbayjany, et al. teaches a method of determining blood glucose using at least two emitters (column. 7, lines 28-31 of Kiani-Azarbayjany, et al.), at least two detectors (column 11, lines 37-38 of Kiani-Azarbayjany, et al.), and a device for changing the volume of blood in the finger (column 6, lines 40-55 of Kiani-Azarbayjany, et al.). The blood volume modulation device wold change the path length of the wavelengths promulgated through the tissue. Also, measurements are taken throughout the blood volume modulation. (column 15, lines 18-36 of Kiani-Azarbayjany, et al.). In regard to claim 2, hemoglobin is determined. (column 16, lines 15-54 of Kiani-Azarbayjany, et al.). In regard to claim 3, the method can be used to determine venous saturation. (column 19, lines 19-23 of Kiani-Azarbayjany, et al. and U.S. Patent 5,632,272 to Diab, et al.). In regard to claim 4, the blood can be arterial or venous. (column 4, lines 43-49 of Kiani-Azarbayjany, et al.). In regard to claim 5, the method includes determining the concentration of the constituent by comparing the radiation path length multiplied by the determined concentration. (column 19, line 15 to column 17, line 2 of Kiani-Azarbayjany, et al.). In regard to claims 6 and 55, multiple light emitters at different wavelengths and detectors are used. (column 7, lines 28-31 and column 11, lines 37-38 of Kiani-Azarbayjany, et al.).

It is well established that a rejection for anticipation under § 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference. *See In re Paulsen,* 30 F.3d 1475, 1478-79, 31 U.S.P.Q. 2d 1671, 1673 (Fed. Cir. 1994); *Scripps Clinic & Research Foundation v. Genentech, Inc.,* 927 F.2d 1565, 18 U.S.P.Q. 2d 1001 (Fed. Cir.1991). *See also American Permahedge, Inc. v. Barcana, Inc.,* 857 F. Supp. 308, 32 U.S.P.Q. 2d 1801, 1807-08 (S.D. NY 1994) ("Prior art anticipates an invention ... if a single prior art reference contains each and every element of the patent at issue, operating in the same fashion to perform the identical function as the patent product. ... Thus, any degree of physical difference between the patented product and the prior art, *no matter how slight,* defeats the claim of anticipation."); *Transco Ex parte*

Levy, 17 U.S.P.Q. 2d 1461, 1462 (Bd. Pat. App. & Int'l 1990) ("[I]t is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference".)

As discussed in detail below, Applicant respectfully submits that Claims 1-6, 53 and 55, as amended, are patentably distinguishable from Kiani-Azarbayjany, et al.

1. Claim 1

As indicated above, Claim 1, as amended, now provides that the volume of a patient's blood is varied by "gravitational force". As is well known, the gravitational force is a constant, internal force. As a result, Applicant has found that when the gravitational force is employed to vary a patient's blood in connection with measuring a blood characteristic, the gravitational force will have little, if any, effect on the blood characteristic being measured.

In contrast, Kiani-Azarbayjany, et al. employs an "external force" to vary the patient's blood volume. There are numerous disadvantages and drawbacks associated with the application of an external force to vary the volume of a patient's blood in conjunction with measuring a blood characteristic or parameter, particularly, absorbance.

As is well known in the art, the application of one or more external forces to a patient's tissue(s) induces many effects on the patient's blood and/or tissues that are virtually impossible to control and measure. The noted induced effects also adversely affect the accuracy of most blood characteristic measurements.

Kiani-Azarbayjany, et al. concede that their "volume change inducing device" alters the very blood characteristics being measured, and in indeterminate amounts. In an attempt to address this issue, Kiani-Azarbayjany, et al. explicitly require "minimal or no movement of the fleshly medium in the area through which light is transmitted."

> The pressure device 152, the cuff 150 and the use of temperature to induce a pulse in the fleshy medium are advantageous in that they can be used with minimal or no movement of the fleshly medium in the area through which light is transmitted. This is possible through inducing the pulse at a location proximal or distal from the area receiving the incident light. The advantage of minimal movement is that movement in the area of the fleshly medium under test causes variation in the detected signal other than due to the varying fluid volume (e.g., blood and interstitial fluid) flow. For instance, physical perturbation in the area of light

> transmission can cause changes in the light coupling to the medium under test resulting in variations in attenuation which are not due to changes in fluid volume in the area of light transmission. (col. 7, l l. 8-22)

Notwithstanding the noted preferred location to induce the pulse, Kiani-Azarbayjany, et al. concede that there are adverse effects (i.e., variations in measurement) resulting from application of the external force, which "comprise additional noise that should be removed for accurate measurement." Moreover, Kiani-Azarbayjany, et al.'s own mathematical formulations reflect that the adverse effects resulting from application of the external force are much greater than the parameter they are attempting to measure.

Further, the application of an external force to a patient's tissue(s) will vary the amount of arterial and venous blood, and alter the ratio thereof. However, since there is no way of determining how much pressure is actually transmitted to the medium or tissue, i.e., the actual pressure acting on the blood, it is virtually impossible to determine the variation in the amount of arterial and venous blood.

Applicant accordingly respectfully submits that the method for non-invasively determining the concentration of a blood constituent embodied in Claim 1 is not anticipated by Kiani-Azarbayjany, et al.

2. Claim 53

Claim 53, as amended, expressly provides that the concentration of the blood constituent is determined by (i) measuring the absorbance of a patient's blood by transmitting radiation through the patient's blood at a prescribed path length, (ii) determining absorbance values at multiples of the path length, and (iii) determining the concentration of the blood constituent based on the absorbance values.

Applicant respectfully submits that Kiani-Azarbayjany, et al. does not disclose determining absorbance values of a patient's blood at multiples of a path length and thereafter determining the concentration of the blood constituent based on the absorbance values. Kiani-Azarbayjany, et al. merely discloses the use of multiple light emitters that are capable of providing radiation at a range of wavelengths.

3. Claim 55

Claim 55, as amended, expressly provides that the concentration of the blood constituent is determined from a first absorbance measured at a first wavelength and a second absorbance measured at a second wavelength.

Applicant submits that Kiani-Azarbayjany, et al. does not disclose measuring a first absorbance of a patient's blood at a first wavelength, measuring a second absorbance of the patient's blood at a second wavelength and determining the concentration of the blood constituent based on the first and second absorbance. Again, Kiani-Azarbayjany, et al. merely discloses the use of multiple light emitters that are capable of providing radiation at a range of wavelengths.

Applicant thus respectfully submits that the methods for non-invasively determining the concentration of a blood constituent embodied in Claims 1-6, 53 and 55, as amended, are not anticipated by Kiani-Azarbayjany, et al. Applicant further submits that Claims 1-6, 53, 55 and new Claims 56-61 define an invention that is unobvious over Kiani-Azarbayjany, et al. Claims 1-6, 53, 55 and 56-61 should thus be deemed allowable.

Applicant has also reviewed the prior art made of record and not relied upon by the Examiner and has found them not to teach or make obvious the present invention.

III. CONCLUSION

Applicant having answered each and every ground of rejection as set forth by the Examiner, and having added no new matter, believes that this response clearly overcomes the references of record, and now submit that all claims in the above-referenced patent application are in condition for allowance and the same is respectfully solicited.

If the Examiner has any further questions or comments, Applicant invites the Examiner to contact his Attorneys of record at the telephone number below to expedite prosecution of the application.

Respectfully submitted,
FRANCIS LAW GROUP

By: _____
Ralph C. Francis
Reg. No. 38,884

Dated: June 12, 2003
1808 Santa Clara Avenue
Alameda, CA 94501
Tel: (510) 769-9800

CERTIFICATE OF MAILING

I hereby certify that this document is being deposited with the United States Postal Service on this date 6-19-03 in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EV348079855US addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Danielle Gragg
Name of person mailing document

Danielle Gragg